From: Bahadori, Tina [bahadori.tina@epa.gov]

Sent: 1/31/2018 7:37:16 PM

To: Lavoie, Emma [Lavoie.Emma@epa.gov]; Bahadori, Tina [Bahadori.Tina@epa.gov]

Subject: Conversation with Lavoie, Emma

Deliberative Process / Ex. 5

From: Thayer, Kris [thayer.kris@epa.gov]

Sent: 1/24/2018 4:43:35 PM

To: Bahadori, Tina [Bahadori.Tina@epa.gov]; Lavoie, Emma [Lavoie.Emma@epa.gov]

Subject: FW: URGENT: Sign Comments to Save IRIS chemical assessments!

Attachments: NRDC Sign On Ltr to NAS IRIS .pdf

Note this paragraph in the NRDC comments

(1) We are concerned that EPA may shift the IRIS program out of the Office of Research and Development (ORD) and into the Office of Chemical Safety and Pollution Prevention (OCSPP) which regulates pesticides and toxic chemicals. This shift would move it from a science and research office to a regulatory policy office under the management of Nancy Beck, a chemical industry lobbyist prior to her recent political appointment at EPA. The chemical industry's opposition to the IRIS program is well-documented and long-standing.6 Dr. Beck's previous foray into developing risk assessment guidelines was a failure, as evidenced by the NAS conclusion that the draft government-wide risk assessment bulletin which she authored while at the Office of Management and Budget (OMB) was "fundamentally flawed" and the unprecedented recommendation for its withdrawal (NAS 2007).7

From: Nachman, Rebecca

Sent: Wednesday, January 24, 2018 10:55 AM

To: Thayer, Kris <thayer.kris@epa.gov>

Subject: FW: URGENT: Sign Comments to Save IRIS chemical assessments!

FYI

From: Rebecca Nachman Redacted

Sent: Wednesday, January 24, 2018 10:53 AM

To: Nachman, Rebecca < nachman.rebecca@epa.gov>

Subject: Fwd: URGENT: Sign Comments to Save IRIS chemical assessments!

----- Forwarded message -----

From: **Jennifer Ames** <illames@berkeley.edu>

Date: Tue, Jan 23, 2018 at 5:23 PM

Subject: Re: URGENT: Sign Comments to Save IRIS chemical assessments!

To: Jennifer Ames <<u>jlames@berkeley.edu</u>>
Cc: "Sass, Jennifer" <<u>jsass@nrdc.org</u>>

Dear all.

Please find attached an updated version of the comments containing some small edits suggested by David Michaels and the signatures that have been collected so far.

On Tue, Jan 23, 2018 at 10:18 AM, Jennifer Ames < ilames@berkeley.edu > wrote:

Hello ISCHE Colleagues,

Jennifer Sass with NRDC (and ISCHE member) has written the attached comments regarding proposed

Administration changes to EPA's Integrated Risk Information System (IRIS). The IRIS program, described below, is on the brink of disaster, and is critical to our work together to protect children from toxic chemicals.

"IRIS identifies and characterizes the potential human health impacts of chemicals and determines "acceptable" levels of exposure to a chemical in air, water, food, or soil. IRIS assessments provide hazard characterizations and dose-response assessments for cancer and non-cancer outcomes. While IRIS assessments are not regulations, they are used by regulators – at the EPA, by local, state and regional governments, and around the world – to set health-based standards for chemicals."

Jennifer Sass (<u>jsass@nrdc.org</u>) will submit these comments to the National Academies of Science meeting next week. If you can, please contact Jennifer Sass to sign on with your name, titles, affiliations, by this Friday, January 26.

Jennifer Sass, Ph.D.
Senior Scientist, Natural Resources Defense Council
And, George Washington University, Dept Environ Occup Health
Tel: 202.289.2362; E: jsass@nrdc.org

Thank you!
Mark Miller
President, ISCHE
Bruce Lanphear
President Elect, ISCHE

Jennifer L. Ames
Coordinator
International Society for Children's Health and the Environment (ISCHE)
http://www.ische.ca/

PhD Candidate in Epidemiology UC Berkeley School of Public Health 101 Haviland Hall Berkeley, CA 94720-7358 From: Bahadori, Tina [Bahadori.Tina@epa.gov]

Sent: 1/23/2018 7:24:15 AM

To: Bahadori, Tina [Bahadori.Tina@epa.gov]
Subject: tracking the evolution of formaldehyde briefings

Attachments: FW: Follow-up; RE: Formaldehyde Science Invited Expert Workshop; FW: Submission of Letter on Behalf of the ACC

Formaldehyde Panel; Letter Submitted on Behalf of the ACC Formaldehyde Panel; Next Steps on Formaldehyde IRIS

Assessment

Deliberative Process / Ex. 5

Message Bahadori, Tina [Bahadori.Tina@epa.gov] From: Sent: 12/20/2017 12:54:46 PM To: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov] CC: Ross, Mary [Ross.Mary@epa.gov]; Jones, Samantha [Jones.Samantha@epa.gov]; D'Amico, Louis [DAmico.Louis@epa.gov]; Lavoie, Emma [Lavoie.Emma@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Ramasamy, Santhini [Ramasamy.Santhini@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Rodan, Bruce [rodan.bruce@epa.gov]; Christian, Megan [Christian.Megan@epa.gov]; Kuhn, Kevin [Kuhn.Kevin@epa.gov]; Fleming, Megan [Fleming.Megan@epa.gov]; Blackburn, Elizabeth [Blackburn.Elizabeth@epa.gov] Subject: Next Steps on Formaldehyde IRIS Assessment Attachments: Talking Points 122017.docx Good Morning Jennifer and Richard, Deliberative Process / Ex. 5 We look forward to hearing back from you. Tina

Tina Bahadori, Sc.D.

Director, National Center for Environmental Assessment (EPA/ORD/NCEA)
National Program Director, Human Health Risk Assessment (EPA/ORD/HHRA)
RRB Room 71210; Telephone: 202-564-7903; Mobile: 202-680-8771

From: Bahadori, Tina

Sent: Thursday, December 7, 2017 8:16 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta.Jennifer@epa.gov>; Yamada, Richard (Yujiro) < yamada.richard@epa.gov>

Subject: formaldehyde

Good morning Jennifer and Richard,

Deliberative Process / Ex. 5

Thanks, Tina From: Mazza, Carl [Mazza.Carl@epa.gov]

1/29/2018 7:49:17 PM Sent:

Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]; Bahadori, Tina [Bahadori.Tina@epa.gov]; Rodan, Bruce To:

[rodan.bruce@epa.gov]

CC: Sasser, Erika [Sasser.Erika@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Shoaff, John [Shoaff.John@epa.gov]

Subject: FW: Letter from the ACC Formaldehyde Panel

Attachments: ACC Formaldehyde Panel Letter to EPA - January 26 2018 - Final.pdf; ATT00001.htm

Deliberative Process / Ex. 5

Carl

From: Orme-Zavaleta, Jennifer

Sent: Friday, January 26, 2018 5:14 PM To: Bahadori, Tina; Yamada, Richard (Yujiro); Rodan, Bruce; Mazza, Carl; Rimer, Kelly Subject: Fwd: Letter from the ACC Formaldehyde Panel

See below and attached.

Deliberative Process / Ex. 5

Thoughts?

Jennifer Orme-Zavaleta, PhD Principal Deputy Assistant Administrator for Science USEPA Office of Research and Development

Personal Privacy / Ex. 6

Begin forwarded message:

From: "White, Kimberly"

<Kimberly_White@americanchemistry.com<mailto:Kimberly_White@americanchemistry.com>>
Date: January 26, 2018 at 4:42:59 PM EST
To: "Orme-Zavaleta.jennifer@Epa.gov<mailto:Orme-Zavaleta.jennifer@Epa.gov>" <Orme-</pre>

Zavaleta.jennifer@Epa.gov<mailto:Orme-Zavaleta.jennifer@Epa.gov>>

Cc: "pruitt.scott@epa.gov<mailto:pruitt.scott@epa.gov>

cpruitt.scott@epa.gov<mailto:pruitt.scott@epa.gov>>,

"wehrum.william@epa.gov<mailto:wehrum.william@epa.gov>"

<wehrum.william@epa.gov<mailto:wehrum.william@epa.gov>>,
"jackson.ryan@epa.gov<mailto:jackson.ryan@epa.gov>" <jac</pre> <jackson.ryan@epa.gov<mailto:jackson.ryan@epa.gov>>

Subject: Letter from the ACC Formaldehyde Panel

Dear Dr. Orme-Zavaleta

Please find attached a letter on behalf of the American Chemistry Council's Formaldehyde Panel.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division

Kimberly_White@americanchemistry.com<mailto:Kimberly_White@americanchemistry.com>

700 2nd Street NE | Washington, DC | 20002 0: (202) 249-6707 C: (202) 341-7602

www.americanchemistry.com<ahttp://www.americanchemistry.com/>

the individual named. If you are not the named addressee do not disseminate, distribute or copy this email. Please notify the sender immediately by email if you have received this email by mistake and delete this email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com<ahttp://www.americanchemistry.com>

From: Mazza, Carl [Mazza.Carl@epa.gov]

Sent: 1/16/2018 4:23:56 PM

To: Bahadori, Tina [Bahadori.Tina@epa.gov]
CC: Lavoie, Emma [Lavoie.Emma@epa.gov]
Subject: RE: Meeting with ACC on Formaldehyde

Would like to listen in if there is a call in #.

From: Bahadori, Tina

Sent: Tuesday, January 16, 2018 6:26 AM

To: Sasser, Erika <Sasser.Erika@epa.gov>; Vasu, Amy <Vasu.Amy@epa.gov>; Axelrad, Daniel <Axelrad.Daniel@epa.gov>;

Mazza, Carl < Mazza. Carl@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>;

Vandenberg, John < Vandenberg. John@epa.gov>; Bussard, David < Bussard. David@epa.gov>

Subject: RE: Meeting with ACC on Formaldehyde

Good Morning Everyone,

Deliberative Process / Ex. 5

Thanks,

Tina

-----Original Appointment-----From: Orme-Zavaleta, Jennifer

Sent: Monday, December 4, 2017 1:55 PM

To: Orme-Zavaleta, Jennifer; Rodan, Bruce; Yamada, Richard (Yujiro); Fleming, Megan; Christian, Megan; Kuhn, Kevin;

Bahadori, Tina

Subject: Meeting with ACC on Formaldehyde

When: Wednesday, January 24, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomRRB41213/ORD

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Monday, December 04, 2017 8:22 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta. Jennifer@epa.gov>

Subject: Follow-up

Dear Dr. Orme-Zavaleta,

Thank you for your initial response to my November 21st letter. Do you have availability for a 1 hour meeting in Washington, DC sometime during the week of January 22nd to discuss further?

Separately, I also wanted to alert you to a recently published article by Mundt et al. titled "Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity". I have appended a copy of the in press version to this email and excerpted the abstract below.

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<u>Regul Toxicol Pharmacol.</u> 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print]

Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity.

Mundt KA¹, Gentry PR², Dell LD², Rodricks JV², Boffetta P³. Author information

Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehydecauses leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" {NRC 2011}. They offered recommendations for improving the IRIS review and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC recommendations and map them to this new science, including extended analysis of epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

KEYWORDS:

Epidemiology; Evidence integration; Hazard evaluation; Mechanistic studies; Regulatory science; Toxicology

++

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

PEERvEPA_1:18-cv-02219_D.D.C.

From: Avery, James [Avery.James@epa.gov]

Sent: 1/9/2018 5:25:31 PM

To: Bahadori, Tina [Bahadori.Tina@epa.gov]; Soto, Vicki [Soto.Vicki@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]

CC: Shams, Dahnish [Shams.Dahnish@epa.gov]

Subject: RE: Slide 11 on Project management

Attachments: IRIS Program Materials to NRC_Part 2.pdf; IRIS Program Materials to NRC_Part 1.pdf

Hi Tina,

Deliberative Process / Ex. 5

The database facilitates project management. Chemical managers will now have a tool for efficiently assigning initial responsibility for addressing comments to assessment team members and clearly defining roles and responsibilities of team members on an assessment.

I've attached Vince's 2 part presentations on addressing the NAS recommendations as background. I'll check to see if there are any materials available that address PM/pm directly.

-James

From: Bahadori, Tina

Sent: Tuesday, January 09, 2018 8:50 AM

To: Soto, Vicki <Soto.Vicki@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>

Cc: Shams, Dahnish <Shams.Dahnish@epa.gov>; Avery, James <Avery.James@epa.gov>

Subject: RE: Slide 11 on Project management

OK, don't worry Vicki. We'll sort this out. James, any insights from you would be most helpful.

Τ.

From: Soto, Vicki

Sent: Tuesday, January 9, 2018 8:35 AM

To: Bahadori, Tina <<u>Bahadori, Tina@epa.gov</u>>; Thayer, Kris <<u>thayer.kris@epa.gov</u>> **Cc:** Shams, Dahnish <<u>Shams.Dahnish@epa.gov</u>>; Avery, James <<u>Avery, James@epa.gov</u>>

Subject: RE: Slide 11 on Project management

Tina – james can help with this. Sorry have to leave.

From: Bahadori, Tina

Sent: Tuesday, January 09, 2018 8:27 AM

To: Soto, Vicki <Soto.Vicki@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>

Cc: Shams, Dahnish <Shams. Dahnish@epa.gov>; Avery, James <Avery. James@epa.gov>

Subject: RE: Slide 11 on Project management

Thanks Vicki. As a slide, I think this is good. Do you know what was said in terms of PM/pm at the 1984 meeting? What information was provided in the background?

Tina

From: Soto, Vicki

Sent: Tuesday, January 9, 2018 8:04 AM

To: Bahadori, Tina Bahadori.Tina@epa.gov">Bahadori.Tina@epa.gov; Thayer, Kris Kris Kris

Subject: Slide 11 on Project management

Hi Tina and Kris,

Attached is a slide that we propose be added to the slide deck that discusses our efforts at project management. It would go in as slide #11.

Let me know if you have comments or suggestions, or if you are OK with me to insert it into the slide deck.

Thanks! Vicki From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]

Sent: 1/23/2018 7:24:15 AM

To: Bahadori, Tina [Bahadori.Tina@epa.gov]
BCC: Tina Bahadori [tbahadori1@gmail.com]

Subject: tracking the evolution of formaldehyde briefings

Attachments: FW: Follow-up; RE: Formaldehyde Science Invited Expert Workshop; FW: Submission of Letter on Behalf of the ACC

Formaldehyde Panel; Letter Submitted on Behalf of the ACC Formaldehyde Panel; Next Steps on Formaldehyde IRIS

Assessment

Deliberative Process / Ex. 5

Appointment

From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]

Sent: 1/22/2018 6:38:15 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]

Subject: FW: Meeting with ACC on Formaldehyde

Location: 41213 RRB/via video to B249; call-in: Personal Privacy / Ex. 6

Start: 1/24/2018 7:00:00 PM **End**: 1/24/2018 8:00:00 PM

Show Time As: Tentative

----Original Appointment----

From: Gentry, Nathan On Behalf Of Orme-Zavaleta, Jennifer

Sent: Tuesday, January 16, 2018 11:23 AM

To: Orme-Zavaleta, Jennifer; Rodan, Bruce; Yamada, Richard (Yujiro); Fleming, Megan; Christian, Megan; Kuhn, Kevin;

Bahadori, Tina

Cc: Vandenberg, John; Thayer, Kris; Lavoie, Emma; Axelrad, Daniel; Ross, Mary; Bussard, David; Mazza, Carl; Sasser,

Erika; Rimer, Kelly; Vasu, Amy

Subject: Meeting with ACC on Formaldehyde

When: Wednesday, January 24, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: 41213 RRB/via video to B249; call-in: Personal Privacy / Ex. 6

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Monday, December 04, 2017 8:22 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta. Jennifer@epa.gov>

Subject: Follow-up

Dear Dr. Orme-Zavaleta,

Thank you for your initial response to my November 21st letter. Do you have availability for a 1 hour meeting in Washington, DC sometime during the week of January 22nd to discuss further?

Separately, I also wanted to alert you to a recently published article by Mundt et al. titled "Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity". I have appended a copy of the in press version to this email and excerpted the abstract below.

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<u>Regul Toxicol Pharmacol.</u> 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print]

Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity.

Mundt KA¹, Gentry PR², Dell LD², Rodricks JV², Boffetta P³. Author information

Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehydecauses leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" {NRC 2011}. They offered recommendations for improving the IRISreview and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC recommendations and map them to this new science, including extended analysis of epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

KEYWORDS:

Epidemiology; Evidence integration; Hazard evaluation; Mechanistic studies; Regulatory science; Toxicology

++

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly_White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]

Sent: 1/22/2018 11:36:29 AM

To: Sasser, Erika [Sasser.Erika@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Vasu, Amy [Vasu.Amy@epa.gov]

Subject: FW: Meeting with ACC on Formaldehyde

Location: 41213 RRB/via video to B249; call-in Personal Privacy / Ex. 6

Start: 1/24/2018 7:00:00 PM **End**: 1/24/2018 8:00:00 PM

Show Time As: Tentative

----Original Appointment----

From: Gentry, Nathan On Behalf Of Orme-Zavaleta, Jennifer

Sent: Tuesday, January 16, 2018 11:23 AM

To: Orme-Zavaleta, Jennifer; Rodan, Bruce; Yamada, Richard (Yujiro); Fleming, Megan; Christian, Megan; Kuhn, Kevin;

Bahadori, Tina

Cc: Vandenberg, John; Thayer, Kris; Lavoie, Emma; Axelrad, Daniel; Ross, Mary; Bussard, David; Mazza, Carl

Subject: Meeting with ACC on Formaldehyde

When: Wednesday, January 24, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: 41213 RRB/via video to B249; call-in: Personal Privacy / Ex. 6

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Monday, December 04, 2017 8:22 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta. Jennifer@epa.gov>

Subject: Follow-up

Dear Dr. Orme-Zavaleta,

Thank you for your initial response to my November 21st letter. Do you have availability for a 1 hour meeting in Washington, DC sometime during the week of January 22nd to discuss further?

Separately, I also wanted to alert you to a recently published article by Mundt et al. titled "Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity". I have appended a copy of the in press version to this email and excerpted the abstract below.

<u>Regul Toxicol Pharmacol.</u> 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print]

Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity.

<u>Mundt KA</u>¹, <u>Gentry PR</u>², <u>Dell LD</u>², <u>Rodricks JV</u>², <u>Boffetta P</u>³. **Author information**

Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehydecauses leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" {NRC 2011}. They offered recommendations for improving the IRISreview and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC recommendations and map them to this new science, including extended analysis of epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

KEYWORDS:

Epidemiology; Evidence integration; Hazard evaluation; Mechanistic studies; Regulatory science; Toxicology

++

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]

Sent: 1/19/2018 4:25:22 PM

To: Sasser, Erika [Sasser.Erika@epa.gov]; Vandenberg, John [Vandenberg.John@epa.gov]; Vasu, Amy

[Vasu.Amy@epa.gov]; Axelrad, Daniel [Axelrad.Daniel@epa.gov]; Mazza, Carl [Mazza.Carl@epa.gov]

CC: Ross, Mary [Ross.Mary@epa.gov]; Lavoie, Emma [Lavoie.Emma@epa.gov]; Thayer, Kris [thayer.kris@epa.gov];

Bussard, David [Bussard.David@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]

Subject: RE: Meeting with ACC on Formaldehyde

Thank you very much. I will make sure you are on the calendar invite. Other names are not required, unless they are going to join separately and need their own calendar invite.

Tina

From: Sasser, Erika

Sent: Friday, January 19, 2018 11:16 AM

To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Vasu, Amy <Vasu.Amy@epa.gov>; Axelrad, Daniel <Axelrad.Daniel@epa.gov>; Mazza, Carl <Mazza.Carl@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>;

Bussard, David <Bussard.David@epa.gov>; Rimer, Kelly <Rimer.Kelly@epa.gov>

Subject: RE: Meeting with ACC on Formaldehyde

Tina, yes we plan to attend. Kelly Rimer, Amy Vasu and I will join John and others in RTP videoconference room B249. Do you need a list of names, if others in OAR express interest in attending?

Thanks

From: Bahadori, Tina

Sent: Tuesday, January 16, 2018 9:18 AM

To: Vandenberg, John <<u>Vandenberg, John@epa.gov</u>>; Sasser, Erika <<u>Sasser, Erika@epa.gov</u>>; Vasu, Amy <<u>Vasu, Amy@epa.gov</u>>; Axelrad, Daniel <<u>Axelrad, Daniel@epa.gov</u>>; Mazza, Carl <<u>Mazza, Carl@epa.gov</u>>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>;

Bussard, David < Bussard. David@epa.gov>

Subject: RE: Meeting with ACC on Formaldehyde

Thanks John – OAR/OP, please let me know if you WILL be able to attend so that I can let Jennifer know. Tina

From: Vandenberg, John

Sent: Tuesday, January 16, 2018 7:57 AM

To: Bahadori, Tina <<u>Bahadori.Tina@epa.gov</u>>; Sasser, Erika <<u>Sasser.Erika@epa.gov</u>>; Vasu, Amy <<u>Vasu.Amy@epa.gov</u>>;

Axelrad, Daniel <<u>Axelrad.Daniel@epa.gov</u>>; Mazza, Carl <<u>Mazza.Carl@epa.gov</u>>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>;

Bussard, David < Bussard. David@epa.gov>

Subject: RE: Meeting with ACC on Formaldehyde

I have reserved B249 for a video connection to RTP from 2-3 on 1/24 -- OAQPS is welcome to join us for this meeting with ACC.

John

From: Bahadori, Tina

Sent: Tuesday, January 16, 2018 6:26 AM

To: Sasser, Erika <Sasser.Erika@epa.gov>; Vasu, Amy <Vasu.Amy@epa.gov>; Axelrad, Daniel <Axelrad.Daniel@epa.gov>;

Mazza, Carl@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>;

Vandenberg, John < Vandenberg, John@epa.gov>; Bussard, David < Bussard, David@epa.gov>

Subject: RE: Meeting with ACC on Formaldehyde

Good Morning Everyone,

Deliberative Process / Ex. 5

Thanks, Tina

-----Original Appointment-----**From:** Orme-Zavaleta, Jennifer

Sent: Monday, December 4, 2017 1:55 PM

To: Orme-Zavaleta, Jennifer; Rodan, Bruce; Yamada, Richard (Yujiro); Fleming, Megan; Christian, Megan; Kuhn, Kevin;

Bahadori, Tina

Subject: Meeting with ACC on Formaldehyde

When: Wednesday, January 24, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomRRB41213/ORD

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Monday, December 04, 2017 8:22 AM

To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>

Subject: Follow-up

Dear Dr. Orme-Zavaleta,

Thank you for your initial response to my November 21st letter. Do you have availability for a 1 hour meeting in Washington, DC sometime during the week of January 22nd to discuss further?

Separately, I also wanted to alert you to a recently published article by Mundt et al. titled "Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity". I have appended a copy of the in press version to this email and excerpted the abstract below.

<u>Regul Toxicol Pharmacol.</u> 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print]

Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity.

 $\frac{\text{Mundt KA}^1, \text{ Gentry PR}^2, \text{ Dell LD}^2, \text{ Rodricks JV}^2, \text{ Boffetta P}^3.}{\text{Author information}}$

Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehydecauses leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" {NRC 2011}. They offered recommendations for improving the IRISreview and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC recommendations and map them to this new science, including extended analysis of epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

KEYWORDS:

Epidemiology; Evidence integration; Hazard evaluation; Mechanistic studies; Regulatory science; Toxicology

++

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From:

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]

Sent: 1/26/2018 11:46:49 PM

Bussard, David [Bussard.David@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara To:

[Glenn.Barbara@epa.gov]

Subject: FW: The gift that keeps on giving

Attachments: ACC Formaldehyde Panel Letter to EPA - January 26 2018 - Final.pdf; ATT00001.htm

Deliberative Process / Ex. 5

From: Orme-Zavaleta, Jennifer

Sent: Friday, January 26, 2018 5:15 PM

To: Bahadori, Tina < Bahadori. Tina@epa.gov >; Yamada, Richard (Yujiro) < yamada.richard@epa.gov >; Rodan, Bruce

<rodan.bruce@epa.gov>; Mazza, Carl <Mazza.Carl@epa.gov>; Rimer, Kelly <Rimer.Kelly@epa.gov>

Subject: Fwd: Letter from the ACC Formaldehyde Panel

See below and attached.

Deliberative Process / Ex. 5

Thoughts?

Jennifer Orme-Zavaleta, PhD Principal Deputy Assistant Administrator for Science USEPA Office of Research and Development

Personal Privacy / Ex. 6

Begin forwarded message:

From: "White, Kimberly" < Kimberly_White@americanchemistry.com>

Date: January 26, 2018 at 4:42:59 PM EST

To: "Orme-Zavaleta.jennifer@Epa.gov" <Orme-Zavaleta.jennifer@Epa.gov> Cc: "pruitt.scott@epa.gov" <pruitt.scott@epa.gov>, "wehrum.william@epa.gov" <wehrum.william@epa.gov>, "jackson.ryan@epa.gov" <jackson.ryan@epa.gov>

Subject: Letter from the ACC Formaldehyde Panel

Dear Dr. Orme-Zavaleta

Please find attached a letter on behalf of the American Chemistry Council's Formaldehyde Panel.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly_White@americanchemistry.com 700 2nd Street NE | Washington, DC | 20002 O: (202) 249-6707 C: (202) 341-7602

www.americanchemistry.com

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From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]

Sent: 1/26/2018 11:45:25 PM

To: Ross, Mary [Ross.Mary@epa.gov]; Jones, Samantha [Jones.Samantha@epa.gov]; Lavoie, Emma

[Lavoie.Emma@epa.gov]; Vandenberg, John [Vandenberg.John@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]; Sasser, Erika [Sasser.Erika@epa.gov]; Vasu, Amy [Vasu.Amy@epa.gov]; Axelrad, Daniel [Axelrad.Daniel@epa.gov]

BCC: Tina Bahadori [tbahadori1@gmail.com]

Subject: The gift that keeps on giving

Attachments: ACC Formaldehyde Panel Letter to EPA - January 26 2018 - Final.pdf; ATT00001.htm

Deliberative Process / Ex. 5

From: Orme-Zavaleta, Jennifer

Sent: Friday, January 26, 2018 5:15 PM

To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Rodan, Bruce

<rodan.bruce@epa.gov>; Mazza, Carl <Mazza.Carl@epa.gov>; Rimer, Kelly <Rimer.Kelly@epa.gov>

Subject: Fwd: Letter from the ACC Formaldehyde Panel

See below and attached.

Deliberative Process / Ex. 5

Thoughts?

Jennifer Orme-Zavaleta, PhD Principal Deputy Assistant Administrator for Science USEPA Office of Research and Development

Personal Privacy / Ex. 6

Begin forwarded message:

From: "White, Kimberly" < Kimberly_White@americanchemistry.com>

Date: January 26, 2018 at 4:42:59 PM EST

To: "Orme-Zavaleta.jennifer@Epa.gov" <Orme-Zavaleta.jennifer@Epa.gov>
Cc: "pruitt.scott@epa.gov" <pruitt.scott@epa.gov>, "wehrum.william@epa.gov" <wehrum.william@epa.gov>, "jackson.ryan@epa.gov" <jackson.ryan@epa.gov>

Subject: Letter from the ACC Formaldehyde Panel

Dear Dr. Orme-Zavaleta

Please find attached a letter on behalf of the American Chemistry Council's Formaldehyde Panel.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

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From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]

Sent: 1/25/2018 5:37:34 PM

To: Axelrad, Daniel [Axelrad.Daniel@epa.gov]
Subject: RE: Meeting with ACC on Formaldehyde

Me too, Dan. I had not heard that she had joined Celanese! Thanks again, Dan.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Tina

From: Axelrad, Daniel

Sent: Thursday, January 25, 2018 12:14 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: RE: Meeting with ACC on Formaldehyde

Hi Tina -

I'm happy to do anything I can to help the IRIS program, so don't hesitate with any requests like this. It was interesting – and I was surprised to see my former AA, Stephanie Daigle, at the meeting.

Deliberative Process / Ex. 5

Thanks,

--Dan.

From: Bahadori, Tina

Sent: Wednesday, January 24, 2018 6:49 PM

To: Mazza, Carl < Mazza. Carl@epa.gov>; Sasser, Erika < Sasser. Erika@epa.gov>; Rimer, Kelly < Rimer. Kelly@epa.gov>;

Vasu, Amy <Vasu.Amy@epa.gov>; Axelrad, Daniel <Axelrad.Daniel@epa.gov>

Cc: Vandenberg, John <\andenberg.John@epa.gov>; Thayer, Kris <\thayer.kris@epa.gov>; Lavoie, Emma

<<u>Lavoie.Emma@epa.gov</u>>; Ross, Mary <<u>Ross.Mary@epa.gov</u>>; Bussard, David <<u>Bussard.David@epa.gov</u>>; Orme-

Zavaleta, Jennifer < Orme-Zavaleta.Jennifer@epa.gov>

Subject: RE: Meeting with ACC on Formaldehyde

Dear OAR and OP colleagues,

Deliberative Process / Ex. 5

W	ith	warm	regard	IS,
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Tina

Tina Bahadori, Sc.D.

Director, National Center for Environmental Assessment (EPA/ORD/NCEA) National Program Director, Human Health Risk Assessment (EPA/ORD/HHRA) RRB Room 71210; Telephone: 202-564-7903; Mobile: 202-680-8771

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10	Daily Check-in 41209 RRB Orme-Zavaleta, Jennifer	•	
11	Hold		
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12 PM		Internal PreBrief - Sen Kamala Harris Staff re: Scientific Integrity Committee Moody, Christina	
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2	Coffee Discussion - Hanson/Yamada Timgad Yamada, Richard (Yujiro)	Meeting with ACC on Formaldehyde 41213 RRB/via video to B249; call-in Personal Privacy / Ex. 6 Orme-Zavaleta, Jennifer	
3	Hold		
		General with Richard Your Office	
4		Brennan, Thomas	
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From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]

Sent: 1/25/2018 8:41:54 AM

To: Lavoie, Emma [Lavoie.Emma@epa.gov]
Subject: RE: Meeting with ACC on Formaldehyde

Deliberative Process / Ex. 5

Т

From: Lavoie, Emma

Sent: Wednesday, January 24, 2018 11:03 PM **To:** Bahadori, Tina <Bahadori.Tina@epa.gov> **Subject:** RE: Meeting with ACC on Formaldehyde

Nice note.

-Emma

Tel: 202 564 7091

From: Bahadori, Tina

Sent: Wednesday, January 24, 2018 6:49 PM

To: Mazza, Carl <Mazza.Carl@epa.gov>; Sasser, Erika <Sasser, Erika@epa.gov>; Rimer, Kelly <Rimer, Kelly@epa.gov>;

Vasu, Amy <\asu.Amy@epa.gov>; Axelrad, Daniel <\axelrad.Daniel@epa.gov>

Cc: Vandenberg, John > Thayer, Kris < thayer, Kris@epa.gov; Lavoie, Emma

<<u>Lavoie.Emma@epa.gov</u>>; Ross, Mary <<u>Ross.Mary@epa.gov</u>>; Bussard, David <<u>Bussard.David@epa.gov</u>>; Orme-

Zavaleta, Jennifer < Orme-Zavaleta.Jennifer@epa.gov>

Subject: RE: Meeting with ACC on Formaldehyde

Dear OAR and OP colleagues,

Deliberative Process / Ex. 5

With warm regards,

Tina

Tina Bahadori, Sc.D.

Director, National Center for Environmental Assessment (EPA/ORD/NCEA)
National Program Director, Human Health Risk Assessment (EPA/ORD/HHRA)
RRB Room 71210; Telephone: 202-564-7903; Mobile: 202-680-8771

PEERvEPA_1:18-cv-02219_D.D.C.

From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]

Sent: 1/16/2018 2:41:51 PM

To: Axelrad, Daniel [Axelrad.Daniel@epa.gov]
Subject: RE: Meeting with ACC on Formaldehyde

THANK YOU!

From: Axelrad, Daniel

Sent: Tuesday, January 16, 2018 9:41 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: RE: Meeting with ACC on Formaldehyde

Hi Tina -

I can attend on 1/24 from 2-3:00.

Thanks for the invite!

--Dan.

From: Bahadori, Tina

Sent: Tuesday, January 16, 2018 6:26 AM

To: Sasser, Erika <Sasser, Erika@epa.gov>; Vasu, Amy <Vasu, Amy@epa.gov>; Axelrad, Daniel <Axelrad, Daniel@epa.gov>;

Mazza, Carl < Mazza. Carl@epa.gov >

Cc: Ross, Mary <Ross.Mary@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>;

Vandenberg, John < Vandenberg, John @epa.gov >; Bussard, David @epa.gov >

Subject: RE: Meeting with ACC on Formaldehyde

Good Morning Everyone,

Deliberative Process / Ex. 5

Thanks,

Tina

-----Original Appointment-----

From: Orme-Zavaleta, Jennifer

Sent: Monday, December 4, 2017 1:55 PM

To: Orme-Zavaleta, Jennifer; Rodan, Bruce; Yamada, Richard (Yujiro); Fleming, Megan; Christian, Megan; Kuhn, Kevin;

Bahadori, Tina

Subject: Meeting with ACC on Formaldehyde

When: Wednesday, January 24, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomRRB41213/ORD

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Monday, December 04, 2017 8:22 AM

To: Orme-Zavaleta, Jennifer < <u>Orme-Zavaleta.Jennifer@epa.gov</u>> **Subject:** Follow-up

Dear Dr. Orme-Zavaleta,

Thank you for your initial response to my November 21st letter. Do you have availability for a 1 hour meeting in Washington, DC sometime during the week of January 22nd to discuss further?

Separately, I also wanted to alert you to a recently published article by Mundt et al. titled "Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity". I have appended a copy of the in press version to this email and excerpted the abstract below.

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<u>Regul Toxicol Pharmacol.</u> 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print]

Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity.

Mundt KA¹, Gentry PR², Dell LD², Rodricks JV², Boffetta P³. Author information

Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehydecauses leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" (NRC 2011). They offered recommendations for improving the IRIS review and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC recommendations and map them to this new science, including extended analysis of epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

KEYWORDS:

Epidemiology; Evidence integration; Hazard evaluation; Mechanistic studies; Regulatory science; Toxicology

++

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002

O: (202) 249-6707 C: (202) 341-7602

www.americanchemistry.com

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12 PM	Orme-Zavaleta, Jennifer	HOLD	Internal PreBrief - Sen Kamala Harris Staff re:	TSCA Bi-Weekly with Bruce Video Locations: DC - RRB51161
1	SES CDP Session for Mentors Navy Hill, SA-4D HO Conf Rm	Biweekly LCR check-in	Moody, Christina	Rodan, Bruce
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11	Weekly General Robbins/Linkins 41245 RRB or via video to Chris in RTP Robbins, Chris		•
1	NHEERL/Robbins Monthly Update Wayne's Office Robbins, Chris		€
2	NCCT Monthly Call-in: Personal Privacy / Ex. 6 Robbins, Chris		€
3	Biweekly L/C Directors Meeting 41245 RRB/D310B/Cindy's office via video; Call-in: Personal Priv Robbins, Chris	/acy / Ex. 6	<i>\$</i> 7
4	General Discussion Orme-Zavaleta/Robbins/Van Drunick 41209 RRB Orme-Zavaleta, Jennifer		
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February 2018 January 24, 2018 January 2018 SuMo TuWe Th Fr Sa SuMo TuWe Th Fr Sa 1 2 3 4 5 6 Wednesday 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 WEDNESDAY 24 $7^{\overline{AM}}$ 8 9 Daily Check-in 41209 RRB 10 Orme-Zavaleta, Jennifer 0 **Chemours Washington Facility** DRA's Meeting Room Personal Privacy / Ex. 6 11 Rodrigues, Cecil **Biweekly Discussion Rodan/Slimak** Mike can call Bruce via Tandberg (or at 202-12 PM Internal PreBrief - Sen Kamala Harris TSCA Bi-Weekly with Bruce Rodan, Bruce Video Locations: DC - RRB51161 (Policyeum) Staff re: Scientific Integrity Committee Rodan, Bruce Moody, Christina 0 Biweekly LCR check-in 1 DCRoomRRB41213/ORD; call-in: Personal Privacy / Ex. 6 Rodan, Bruce 0 2 Meeting with ACC on Formaldehyde 41213 RRB/via video to B249; call-in: Personal Privacy / Ex. 6 Orme-Zavaleta, Jennifer 3 4 5 Daily Check-in Rodan/Fleming RRB 41226 Rodan, Bruce \odot 6

January 24, 2018 Wednesday		January 2018 SuMo TuWe Th Fr Sa 1 2 3 4 5 6 7 8 9 10 11 12 13 4 5 6 7 8 9 10 14 15 16 17 18 19 20 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 February 2018 SuMo TuWe Th Fr Sa 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31
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1	HOLD	
2 PM		Internal PreBrief - Sen Kamala Harris Staff re: Scientific Integrity Committee Moody, Christina
2	Coffee Discussion - Hanson/Yamada Timgad Yamada, Richard (Yujiro)	Meeting with ACC on Formaldehyde 41213 RRB/via video to B249; call-in Personal Privacy / Ex. Orme-Zavaleta, Jennifer
3	Hold	General with Richard
4		Your Office Brennan, Thomas
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January 24, 2018 Wednesday		January 2018 SuMo TuWe Th Fr Sa 1 2 3 4 5 6 7 8 9 10 11 12 13 4 5 6 7 8 9 10 14 15 16 17 18 19 20 11 12 13 14 15 16 17 21 22 23 24 25 26 27 18 19 20 21 22 23 24 28 29 30 31 February 2018 SuMo TuWe Th Fr Sa 4 5 6 7 8 9 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28 29 30 31 February 2018 SuMo TuWe Th Fr Sa 1 2 3 1 2 3 2 5 6 7 8 9 10 11 12 13 14 15 16 17 21 22 23 24 25 26 27 28
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8	Daily Check-in w/ MER RR 41226	Weekly General Radzikowski/Margolies
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Biweekly L/C Directors Meeting 41245 RRB/D310B/Cindy's office via video; Call-in: Persona Robbins, Chris	l Privacy / Ex. 6	0

7:45pm - 9:20pm Private Appointment		***
	Daily Check-in 41209 RRB Orme-Zavaleta, Jennifer General Liz's Office Blackburn, Elizabeth Daily check in Dale/Liz Liz's office Blackburn, Elizabeth Biweekly L/C Directors Meeting 41245 RRB/D310B/Cindy's office via video; Call-in: Persona	Main Sum Tuwe Th Fr Sa

From: Blackburn, Elizabeth [Blackburn.Elizabeth@epa.gov]

Sent: 1/22/2018 6:05:12 PM

To: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]

CC: Hubbard, Carolyn [Hubbard.Carolyn@epa.gov]

Subject: FW: Breaking News: The U.S. government is close to reopening: Senate Democrats helped advance a stopgap bill

after a G.O.P. pledge to continue immigration talks

Deliberative Process / Ex. 5

Liz

Liz Blackburn Chief of Staff EPA Office of Research and Development 202-564-2192

Mobile: 202-436-2453

From: NYTimes.com News Alert [mailto:nytdirect@nytimes.com]

Sent: Monday, January 22, 2018 12:49 PM

To: Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>

Subject: Breaking News: The U.S. government is close to reopening: Senate Democrats helped advance a stopgap bill

after a G.O.P. pledge to continue immigration talks

	Add nytdirect@nytimes.com to your address book. Add nytdirect@nytimes.com to your address book.
Breaking News A	lert
January 22, 2018	NYTimes.com »

BREAKING NEWS

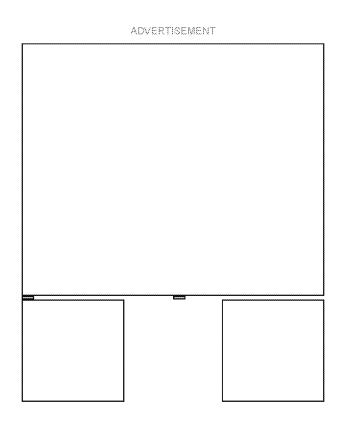
The U.S. government is close to reopening: Senate Democrats helped advance a stopgap bill after a G.O.P. pledge to continue immigration talks

Monday, January 22, 2018 12:45 PM EST

The Senate voted overwhelmingly to end the three-day old government shutdown, with Democrats joining Republicans to clear the way for a short-term spending package that would fund the government through Feb. 8 in exchange for a promise from Republican leaders to address the fate of the young undocumented immigrants known as Dreamers.

"In a few hours, the government will reopen," said Senator Chuck Schumer of New York, the Democratic leader. "We have a lot to do."

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,	

Message

From: Jackson, Ryan [jackson.ryan@epa.gov]

Sent: 1/9/2018 7:01:54 PM

To: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]
CC: Yamada, Richard (Yujiro) [yamada.richard@epa.gov]

Subject: RE: follow up on formaldehyde

Deliberative Process / Ex. 5

From: Orme-Zavaleta, Jennifer

Sent: Tuesday, January 9, 2018 7:31 AM **To:** Jackson, Ryan <jackson.ryan@epa.gov>

Cc: Yamada, Richard (Yujiro) <yamada.richard@epa.gov>

Subject: follow up on formaldehyde

Deliberative Process / Ex. 5

Thanks

jennifer

Jennifer Orme-Zavaleta, PhD Principal Deputy Assistant Administrator for Science USEPA Office of Research and Development

Personal Privacy / Ex. 6

orme-zavaleta.jennifer@epa.gov

From: Robbins, Chris [Robbins.Chris@epa.gov]

Sent: 1/20/2018 1:36:22 AM

To: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]

Subject: Re: Request for travel approval

I must be psychic!

Sent from my iPad

On Jan 19, 2018, at 8:34 PM, Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov> wrote:

Deliberative Process / Ex. 5

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
USEPA Office of Research and Development

Personal Privacy / Ex. 6

On Jan 19, 2018, at 8:31 PM, Robbins, Chris < Robbins. Chris@epa.gov> wrote:

Hi David,

Deliberative Process / Ex. 5

Chris

Sent from my iPad

On Jan 19, 2018, at 8:19 PM, Bloom, David Bloom.David@epa.gov wrote:

Chris,

Deliberative Process / Ex. 5

Sent from my iPhone

On Jan 19, 2018, at 8:11 PM, Robbins, Chris Robbins.Chris@epa.gov> wrote:

Hi David,

Here is some additional information regarding the trip to Baton Rouge along with the Region 6 personnel. Our

Deliberative Process / Ex. 5

This meeting is with several Louisiana state agencies and their staff to gather information relating to the rules, regulations and opportunities available to dairy farmers in Louisiana. This meeting is part of the Region 6 RESES project working with dairy farmers and follows up on a series of three workshops that were held to engage dairy farmers, community leaders, and interested state and federal agency staff in Region 6 and Louisiana to solve environmental problems related to dairy farms. ORD is co-leading this effort with Louisiana DEQ and Region 6. Region 6 employees (Jerry Saunders, Stephanie Meyers) have requested clearance to attend.

Regarding Jennifer and I, several things we want to point out. Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thanks for yo further!	our consideration and happy to discuss
Chris	
Sent from my	/ iPad
	018, at 7:41 PM, Bloom, David d@epa.gov> wrote:
Chris Delibe	erative Process / Ex. 5 David
Sent	from my iPhone
	an 19, 2018, at 7:38 PM, Robbins, < <u>Robbins.Chris@epa.gov</u> > wrote:
	Hi David,
	Deliberative Process / Ex. 5
	Deliberative Process / Ex. 5
	Thx
	Sent from my iPhone

On Jan 19, 2018, at 7:25 PM, Bloom, David < Bloom.David@epa.gov > wrote:



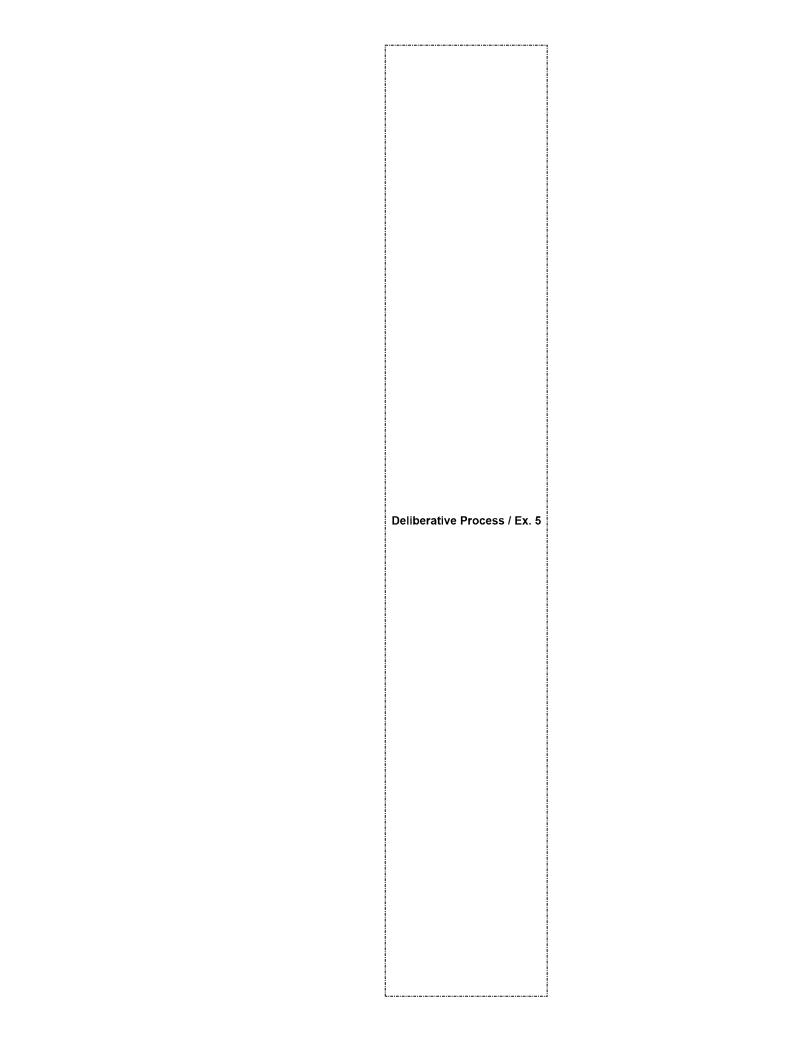
Sent from my

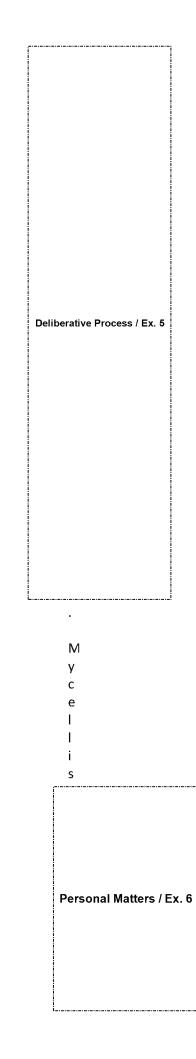
iPhone

On Jan 19, 2018, at 5:53 PM, Robbins , Chris <<u>Robbins.Chris</u> @epa.g

wrote:

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р m е n t 9 1 9 5 4 1 0 6 0 5 < O R D P r i 0 r T r a \mathbf{v} e \mathbf{S} t J a n u a r У 1 9

0 8 1 . d o c From: Bloom, David [Bloom.David@epa.gov]

Sent: 1/20/2018 1:32:24 AM

To: Robbins, Chris [Robbins.Chris@epa.gov]

CC: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]

Subject: Re: Request for travel approval

Chris,

Thanks for your note.

Deliberative Process / Ex. 5 David

Sent from my iPhone

On Jan 19, 2018, at 8:31 PM, Robbins, Chris < Robbins. Chris@epa.gov> wrote:

Hi David,

Deliberative Process / Ex. 5

Chris

Sent from my iPad

On Jan 19, 2018, at 8:19 PM, Bloom, David <Bloom.David@epa.gov> wrote:

Chris,

Deliberative Process / Ex. 5

Sent from my iPhone

On Jan 19, 2018, at 8:11 PM, Robbins, Chris < Robbins, Chris@epa.gov> wrote:

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Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

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Regarding Jennifer and I, several things we want to point out.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thanks for your consideration and happy to discuss further!

Chris

Sent from my iPad

On Jan 19, 2018, at 7:41 PM, Bloom, David < <u>Bloom.David@epa.gov</u>> wrote:

Chris, Delibera	ative Proc	ess / Ex	. 5 David	
Sent fro	om my iF	hone		
			8 PM, Robbins, Chr ov> wrote:	is
	Hi Davi	d,		
	Delii	berat	ive Process /	Ex. 5
	Thx			
	Sent fro	om my i	Phone	
			8, at 7:25 PM, Bloo David@epa.gov> w	
		Chris,		
		Delibe	rative Process / Ex. !	5
		Sent fr	om my iPhone	
		PM, Ro	19, 2018, at 5:53 bbbins, Chris ins.Chris@epa.go ite:	
			Hi David,	
			Deliberative Process / Ex. 5	



Chris

Christo pher S. Robbins Deputy Assista nt Admini strator for Manag ement (Acting) Office of Researc h and Develo pment (919)541-0605

<ORD
Priorit
y
Travel
list Januar
y 19
2081.d</pre>

ocx>

From: Hubbard, Carolyn [Hubbard.Carolyn@epa.gov]

Sent: 1/18/2018 5:15:41 PM

To: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]

CC: Robbins, Chris [Robbins.Chris@epa.gov]; Rodan, Bruce [rodan.bruce@epa.gov]; Blackburn, Elizabeth

[Blackburn.Elizabeth@epa.gov]; Radzikowski, Mary Ellen [Radzikowski.Maryellen@epa.gov]; Christian, Megan

[Christian.Megan@epa.gov]

Subject: ORD Weekly Report January 18
Attachments: ORD weekly Update Jan 18.docx

Deliberative Process / Ex. 5

To: Weekly Report Group@epa.gov

CC: hubbard.carolyn@epa.gov; Blackburn.elizabeth@epa.gov; Gwinn.maureen@epa.gov; Rodan.bruce@epa.gov; radzikowski.maryellen@epa.gov; Robbins.chris@epa.gov; Breen.Barry@epa.gov; dunham.sarah@epa.gov; beck.nancy@epa.gov; Yamada.richard@epa.gov; glenn.trey@epa.gov; forsgren.lee@epa.gov; nishida.jane@epa.gov; servidio.cosmo@epa.gov; Benevento.douglas@epa.gov; gulliford.jim@epa.gov; Lopez.peter@epa.gov; wagner.kenneth@epa.gov; darwin.henry@epa.gov; bodine.susan@epa.gov; Ross.david@epa.gov; stepp.cathy@epa.gov; idsal.anne@epa.gov; wehrum.bill@epa.gov;

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From: Orme-Zavaleta, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C5A111DC377411595E5B24B5D96146B-ORME-ZAVALETA, JENNIFER]

Sent: 1/18/2018 5:32:43 PM

To: Hubbard, Carolyn [Hubbard.Carolyn@epa.gov]

CC: Robbins, Chris [Robbins.Chris@epa.gov]; Rodan, Bruce [rodan.bruce@epa.gov]; Blackburn, Elizabeth

[Blackburn.Elizabeth@epa.gov]; Radzikowski, Mary Ellen [Radzikowski.Maryellen@epa.gov]; Christian, Megan

[Christian.Megan@epa.gov]

Subject: Re: ORD Weekly Report January 18

Deliberative Process / Ex. 5

Sent from my iPad

On Jan 18, 2018, at 12:15 PM, Hubbard, Carolyn < Hubbard. Carolyn@epa.gov> wrote:

Deliberative Process / Ex. 5

To: Weekly Report Group@epa.gov

CC: hubbard.carolyn@epa.gov; Blackburn.elizabeth@epa.gov; Gwinn.maureen@epa.gov; Rodan.bruce@epa.gov; radzikowski.maryellen@epa.gov; Robbins.chris@epa.gov; Breen.Barry@epa.gov; dunham.sarah@epa.gov; beck.nancy@epa.gov; Yamada.richard@epa.gov; glenn.trey@epa.gov; forsgren.lee@epa.gov; nishida.jane@epa.gov; servidio.cosmo@epa.gov; Benevento.douglas@epa.gov; gulliford.jim@epa.gov; Lopez.peter@epa.gov; wagner.kenneth@epa.gov; darwin.henry@epa.gov; bodine.susan@epa.gov; Ross.david@epa.gov; stepp.cathy@epa.gov; idsal.anne@epa.gov; wehrum.bill@epa.gov;

Administrator,



<ORD weekly Update Jan 18.docx>

Message

From: Orme-Zavaleta, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C5A111DC377411595E5B24B5D96146B-ORME-ZAVALETA, JENNIFER]

Sent: 1/16/2018 4:17:49 PM

To: Gentry, Nathan [Gentry.Nathan@epa.gov]
Subject: FW: Meeting with ACC on Formaldehyde

Could you add for the mtg on the 24th? thanks

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
USEPA Office of Research and Development

Personal Privacy / Ex. 6

orme-zavaleta.jennifer@epa.gov

From: Vandenberg, John

Sent: Tuesday, January 16, 2018 11:13 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta. Jennifer@epa.gov>

Subject: RE: Meeting with ACC on Formaldehyde

We have reserved B249 in RTP for a video link.

-----Original Appointment-----From: Orme-Zavaleta, Jennifer

Sent: Tuesday, January 16, 2018 9:48 AM

To: Orme-Zavaleta, Jennifer; Rodan, Bruce; Yamada, Richard (Yujiro); Fleming, Megan; Christian, Megan; Kuhn, Kevin;

Bahadori, Tina

Cc: Vandenberg, John; Thayer, Kris; Lavoie, Emma; Axelrad, Daniel; Ross, Mary; Bussard, David

Subject: FW: Meeting with ACC on Formaldehyde

When: Wednesday, January 24, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomRRB41213/ORD

-----Original Appointment-----From: Orme-Zavaleta, Jennifer

Sent: Monday, December 4, 2017 1:55 PM

To: Orme-Zavaleta, Jennifer; Rodan, Bruce; Yamada, Richard (Yujiro); Fleming, Megan; Christian, Megan; Kuhn, Kevin;

Bahadori, Tina

Subject: Meeting with ACC on Formaldehyde

When: Wednesday, January 24, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: DCRoomRRB41213/ORD

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Monday, December 04, 2017 8:22 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta. Jennifer@epa.gov>

Subject: Follow-up

Dear Dr. Orme-Zavaleta,

Thank you for your initial response to my November 21st letter. Do you have availability for a 1 hour meeting in Washington, DC sometime during the week of January 22nd to discuss further?

Separately, I also wanted to alert you to a recently published article by Mundt et al. titled "Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity". I have appended a copy of the in press version to this email and excerpted the abstract below.

+++++

<u>Regul Toxicol Pharmacol.</u> 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print]

Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity.

<u>Mundt KA¹</u>, <u>Gentry PR²</u>, <u>Dell LD²</u>, <u>Rodricks JV²</u>, <u>Boffetta P³</u>. **Author information**

Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehydecauses leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" {NRC 2011}. They offered recommendations for improving the IRIS review and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC recommendations and map them to this new science, including extended analysis of epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

KEYWORDS:

Epidemiology; Evidence integration; Hazard evaluation; Mechanistic studies; Regulatory science; Toxicology

++

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly_White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602

www.americanchemistry.com

Appointment

From: Gentry, Nathan [Gentry.Nathan@epa.gov]

Sent: 1/16/2018 8:22:43 PM

To: Rodan, Bruce [rodan.bruce@epa.gov]; Yamada, Richard (Yujiro) [yamada.richard@epa.gov]; Fleming, Megan

[Fleming.Megan@epa.gov]; Christian, Megan [Christian.Megan@epa.gov]; Kuhn, Kevin [Kuhn.Kevin@epa.gov];

Bahadori, Tina [Bahadori.Tina@epa.gov]

CC: Vandenberg, John [Vandenberg.John@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]; Lavoie, Emma

[Lavoie.Emma@epa.gov]; Axelrad, Daniel [Axelrad.Daniel@epa.gov]; Ross, Mary [Ross.Mary@epa.gov]; Bussard,

David [Bussard.David@epa.gov]; Mazza, Carl [Mazza.Carl@epa.gov]

Subject: Meeting with ACC on Formaldehyde

Location: 41213 RRB/via video to B249; call-in Personal Privacy / Ex. 6

Start: 1/24/2018 7:00:00 PM **End**: 1/24/2018 8:00:00 PM

Show Time As: Tentative

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Monday, December 04, 2017 8:22 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta. Jennifer@epa.gov>

Subject: Follow-up

Dear Dr. Orme-Zavaleta,

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<u>Regul Toxicol Pharmacol.</u> 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print]

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Mundt KA¹, Gentry PR², Dell LD², Rodricks JV², Boffetta P³. Author information

Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehydecauses leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" {NRC 2011}. They offered recommendations for improving the IRIS review and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC recommendations and map them to this new science, including extended analysis of

epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

KEYWORDS:

Epidemiology; Evidence integration; Hazard evaluation; Mechanistic studies; Regulatory science; Toxicology

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Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly_White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602

www.americanchemistry.com

Appointment

From: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]

Sent: 1/16/2018 2:47:55 PM

To: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]; Rodan, Bruce [rodan.bruce@epa.gov]; Yamada, Richard

(Yujiro) [yamada.richard@epa.gov]; Fleming, Megan [Fleming.Megan@epa.gov]; Christian, Megan

[Christian.Megan@epa.gov]; Kuhn, Kevin [Kuhn.Kevin@epa.gov]; Bahadori, Tina [Bahadori.Tina@epa.gov]

CC: Vandenberg, John [Vandenberg.John@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]; Lavoie, Emma

[Lavoie.Emma@epa.gov]; Axelrad, Daniel [Axelrad.Daniel@epa.gov]; Ross, Mary [Ross.Mary@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Mazza, Carl [Mazza.Carl@epa.gov]; Sasser, Erika [Sasser.Erika@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Vasu, Amy [Vasu.Amy@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn,

Barbara [Glenn.Barbara@epa.gov]

Subject: Meeting with ACC on Formaldehyde

Location: 41213 RRB/via video to B249; call-in: Personal Privacy / Ex. 6

Start: 1/24/2018 7:00:00 PM **End**: 1/24/2018 8:00:00 PM

Show Time As: Busy

I have reserved B249 for a video connection to RTP from 2-3 on 1/24 -- OAQPS is welcome to join us for this meeting with ACC.

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Monday, December 04, 2017 8:22 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta.Jennifer@epa.gov>

Subject: Follow-up

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Mundt KA¹, Gentry PR², Dell LD², Rodricks JV², Boffetta P³.

<u>Author information</u>

Ahetraet

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KEYWORDS:

Epidemiology; Evidence integration; Hazard evaluation; Mechanistic studies; Regulatory science; Toxicology

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Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602

www.americanchemistry.com

Message

From: Bahadori, Tina [Bahadori.Tina@epa.gov]

Sent: 1/26/2018 11:45:25 PM

To: Ross, Mary [Ross.Mary@epa.gov]; Jones, Samantha [Jones.Samantha@epa.gov]; Lavoie, Emma

[Lavoie.Emma@epa.gov]; Vandenberg, John [Vandenberg.John@epa.gov]; Thayer, Kris [thayer.kris@epa.gov]; Sasser, Erika [Sasser.Erika@epa.gov]; Vasu, Amy [Vasu.Amy@epa.gov]; Axelrad, Daniel [Axelrad.Daniel@epa.gov]

Subject: The gift that keeps on giving

Attachments: ACC Formaldehyde Panel Letter to EPA - January 26 2018 - Final.pdf; ATT00001.htm

Deliberative Process / Ex. 5

From: Orme-Zavaleta, Jennifer

Sent: Friday, January 26, 2018 5:15 PM

To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Rodan, Bruce

<rodan.bruce@epa.gov>; Mazza, Carl <Mazza.Carl@epa.gov>; Rimer, Kelly <Rimer.Kelly@epa.gov>

Subject: Fwd: Letter from the ACC Formaldehyde Panel

See below and attached.

Deliberative Process / Ex. 5

Thoughts?

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
USEPA Office of Research and Development

Personal Privacy / Ex. 6

Begin forwarded message:

From: "White, Kimberly" < Kimberly_White@americanchemistry.com>

Date: January 26, 2018 at 4:42:59 PM EST

To: "Orme-Zavaleta.jennifer@Epa.gov" <Orme-Zavaleta.jennifer@Epa.gov>
Cc: "pruitt.scott@epa.gov" <pruitt.scott@epa.gov", "wehrum.william@epa.gov"
<wehrum.william@epa.gov>, "jackson.ryan@epa.gov" <jackson.ryan@epa.gov>

Subject: Letter from the ACC Formaldehyde Panel

Dear Dr. Orme-Zavaleta

Please find attached a letter on behalf of the American Chemistry Council's Formaldehyde Panel.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly_White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

this email by mistake and delete this email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

From: Vandenberg, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCAE2B98A04540FB8D099F9D4DEAD690-VANDENBERG, JOHN]

Sent: 1/24/2018 7:22:10 PM

To: Philpott, Olivia [Philpott.Olivia@epa.gov]
Subject: Fwd: Meeting with ACC on Formaldehyde

Attachments: background.pdf; ATT00001.htm; formaldehyde ppt.pdf; ATT00002.htm; one pager.pdf; ATT00003.htm; paper.pdf;

ATT00004.htm

Can you print off the attached slides 2 to a page and 5 copies ASAP? I'm in b249

Thanks!

Sent from my iPhone

Begin forwarded message:

From: "Kuhn, Kevin" < Kuhn. Kevin@epa.gov>

To: "Orme-Zavaleta, Jennifer" <Orme-Zavaleta, Jennifer@epa,gov>, "Rodan, Bruce"

<<u>rodan.bruce@epa.gov</u>>, "Yamada, Richard (Yujiro)" <<u>yamada.richard@epa.gov</u>>, "Fleming, Megan"

<<u>Fleming.Megan@epa.gov</u>>, "Christian, Megan" <<u>Christian.Megan@epa.gov</u>>, "Bahadori, Tina"

<Bahadori.Tina@epa.gov>

Cc: "Vandenberg, John" < Vandenberg, John@epa.gov>, "Thayer, Kris" < thayer.kris@epa.gov>, "Lavoie,

Emma" <<u>Lavoie.Emma@epa.gov</u>>, "Axelrad, Daniel" <<u>Axelrad.Daniel@epa.gov</u>>, "Ross, Mary"

<<u>Ross.Mary@epa.gov</u>>, "Bussard, David" <<u>Bussard.David@epa.gov</u>>, "Mazza, Carl"

<<u>Mazza.Carl@epa.gov</u>>, "Sasser, Erika" <<u>Sasser.Erika@epa.gov</u>>, "Rimer, Kelly" <<u>Rimer.Kelly@epa.gov</u>>,

"Vasu, Amy" <<u>Vasu.Amy@epa.gov</u>>, "Kraft, Andrew" <<u>Kraft.Andrew@epa.gov</u>>, "Glenn, Barbara"

<<u>Glenn.Barbara@epa.gov</u>>

Subject: RE: Meeting with ACC on Formaldehyde

Hi All,

Please find attached the background documents under discussion.

Kevin Kuhn ORD/EPA (202) 564-4835

Mobile: (202) 309-3969

-----Original Appointment-----From: Orme-Zavaleta, Jennifer

Sent: Monday, December 4, 2017 12:07 PM

To: Orme-Zavaleta, Jennifer; Rodan, Bruce; Yamada, Richard (Yujiro); Fleming, Megan; Christian, Megan;

Kuhn, Kevin; Bahadori, Tina

Cc: Vandenberg, John; Thayer, Kris; Lavoie, Emma; Axelrad, Daniel; Ross, Mary; Bussard, David; Mazza,

Carl; Sasser, Erika; Rimer, Kelly; Vasu, Amy; Kraft, Andrew; Glenn, Barbara

Subject: Meeting with ACC on Formaldehyde

When: Wednesday, January 24, 2018 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: 41213 RRB/via video to B249; call-in Personal Privacy / Ex. 6

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Monday, December 04, 2017 8:22 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta.Jennifer@epa.gov>

Subject: Follow-up

Dear Dr. Orme-Zavaleta,

Thank you for your initial response to my November 21st letter. Do you have availability for a 1 hour meeting in Washington, DC sometime during the week of January 22nd to discuss further?

Separately, I also wanted to alert you to a recently published article by Mundt et al. titled "Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity". I have appended a copy of the in press version to this email and excerpted the abstract below.

<u>Regul Toxicol Pharmacol.</u> 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print]

Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulator y implications of new science in evaluating formaldehyde leukemogenicity.

 $\frac{\text{Mundt KA}^1, \ \text{Gentry PR}^2, \ \text{Dell LD}^2, \ \text{Rodricks JV}^2, \ \text{Boffetta P}^3.}{\text{Author information}}$

Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehydecauses leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" {NRC 2011}. They offered recommendations for improving the IRISreview and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC recommendations and map them to this new science, including extended analysis of epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

KEYWORDS:

Epidemiology;	Evidence	integration;	Hazard	evaluation;	Mechanistic	studies;	Regulatory	science;
Toxicology								

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly_White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

Appointment

Ross, Christine [Ross.Christine@epa.gov] From:

Sent: 10/25/2016 3:23:18 PM

To: Ross, Christine [Ross.Christine@epa.gov]; Robinan Gentry [rgentry@ramboll.com]; Ken Mundt

[kmundt@ramboll.com]; Cogliano, Vincent [cogliano.vincent@epa.gov]; Perovich, Gina [Perovich.Gina@epa.gov];

Kraft, Andrew [Kraft.Andrew@epa.gov]; Birchfield, Norman [Birchfield.Norman@epa.gov]; Bussard, David

[Bussard.David@epa.gov]; Jones, Samantha [Jones.Samantha@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov];

Jinot, Jennifer [Jinot.Jennifer@epa.gov]; Bateson, Thomas [Bateson.Thomas@epa.gov]; Fritz, Jason

[Fritz.Jason@epa.gov]; Johnson, Antoinette [Johnson.Antoinette@epa.gov]; West, Jeremy [West.Jeremy@epa.gov]; Soto, Vicki [Soto.Vicki@epa.gov]; Slimak, Michael [Slimak.Michael@epa.gov]; Ross, Mary [Ross.Mary@epa.gov];

Meadows, Leslie [Meadows.Leslie@epa.gov]

CC: Shams, Dahnish [Shams.Dahnish@epa.gov]

Subject: Formaldehyde

Attachments: Final New Formaldehyde Science Ramboll Environ_110716_final.pdf

Location: DCRoomPYS11100-Potomac

Start: 11/7/2016 7:00:00 PM End: 11/7/2016 8:00:00 PM

Show Time As: Tentative

Meeting with Dr. Ken Mundt and Dr. Robinan Gentry of Ramboll Environment, to discuss the new science and analyses relevant to the EPA IRIS Tox review of Formaldehyde.

For persons wishing to call in, the number is:

Redacted ; conference code:

Room changed to: S-11621

Good morning:

I sent you a copy of the draft presentation for the formaldehyde meeting today. I have now received the final version, and it is attached.



Final New

Formaldehyde S...

Thank you.

CC:

From: Ross, Christine [Ross.Christine@epa.gov]

Sent: 11/7/2016 4:37:32 PM

To: Robinan Gentry [rgentry@ramboll.com]; Ken Mundt [kmundt@ramboll.com]; Cogliano, Vincent

[cogliano.vincent@epa.gov]; Perovich, Gina [Perovich.Gina@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Birchfield, Norman [Birchfield.Norman@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Jones, Samantha [Jones.Samantha@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Jinot, Jennifer [Jinot.Jennifer@epa.gov];

Bateson, Thomas [Bateson.Thomas@epa.gov]; Fritz, Jason [Fritz.Jason@epa.gov]; Johnson, Antoinette

[Johnson.Antoinette@epa.gov]; West, Jeremy [West.Jeremy@epa.gov]; Soto, Vicki [Soto.Vicki@epa.gov]; Slimak, Michael [Slimak.Michael@epa.gov]; Ross, Mary [Ross.Mary@epa.gov]; Meadows, Leslie [Meadows.Leslie@epa.gov]

Shams, Dahnish [Shams.Dahnish@epa.gov]

Subject: Formaldehyde

Attachments: Final New Formaldehyde Science Ramboll Environ_110716_final.pdf

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For persons wishing to call in, the number is:

Personal Privacy / Ex. 6

Room changed to: S-11621

Good morning:

I sent you a copy of the draft presentation for the formaldehyde meeting today. I have now received the final version, and it is attached.

Å., Per

Final New Formaldehyde S...

Thank you.

From: Thayer, Kris [thayer.kris@epa.gov]

Sent: 12/4/2017 3:03:39 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Bussard, David

[Bussard.David@epa.gov]; Bateson, Thomas [Bateson.Thomas@epa.gov]

CC: Bahadori, Tina [Bahadori.Tina@epa.gov]

Subject: Fwd: Follow-up

Attachments: Mundt et al 2017 - Six Year aftr NRC Review.pdf; ATT00001.htm

FYI

Sent from my iPhone

Begin forwarded message:

From: "Orme-Zavaleta, Jennifer" < Orme-Zavaleta. Jennifer@epa.gov>

Date: December 4, 2017 at 8:49:33 AM EST

To: "Bahadori, Tina" <Bahadori.Tina@epa.gov>, "Thayer, Kris" <thayer.kris@epa.gov>

Subject: FW: Follow-up

To start your week...

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator for Science
USEPA Office of Research and Development



orme-zavaleta.jennifer@epa.gov

From: White, Kimberly [mailto:Kimberly White@americanchemistry.com]

Sent: Monday, December 04, 2017 8:22 AM

To: Orme-Zavaleta, Jennifer < Orme-Zavaleta.Jennifer@epa.gov>

Subject: Follow-up

Dear Dr. Orme-Zavaleta,

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Separately, I also wanted to alert you to a recently published article by Mundt et al. titled "Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulatory implications of new science in evaluating formaldehyde leukemogenicity". I have appended a copy of the in press version to this email and excerpted the abstract below.

<u>Regul Toxicol Pharmacol.</u> 2017 Nov 17. pii: S0273-2300(17)30363-X. doi: 10.1016/j.yrtph.2017.11.006. [Epub ahead of print] Six years after the NRC Review of EPA's Draft IRIS Toxicological Review of Formaldehyde: Regulator y implications of new science in evaluating formaldehyde leukemogenicity.

<u>Mundt KA¹</u>, <u>Gentry PR²</u>, <u>Dell LD²</u>, <u>Rodricks JV²</u>, <u>Boffetta P³</u>. <u>Author information</u> Abstract

Shortly after the International Agency for Research on Cancer (IARC) determined that formaldehyde causes leukemia, the United States Environmental Protection Agency (EPA) released its Draft IRIS Toxicological Review of Formaldehyde, also concluding that formaldehydecauses leukemia. Peer review of the EPA Draft IRIS Assessment by a National Academy of Science committee noted that "causal determinations are not supported by the narrative provided in the draft" {NRC 2011}. They offered recommendations for improving the IRISreview and identified several important research gaps. Over the six years since the NRC peer review, significant new science has been published. We identify and summarize key NRC recommendations and map them to this new science, including extended analysis of epidemiological studies, updates of earlier occupational cohort studies, toxicological experiments using a sensitive mouse strain, mechanistic studies examining the role of exogenous versus endogenous formaldehyde in bone marrow, and several critical reviews. With few exceptions, new findings are consistently negative, and integration of all available evidence challenges the earlier conclusions that formaldehyde causes leukemia. Given formaldehyde's commercial importance, environmental ubiquity and endogenous production, accurate hazard classification and risk evaluation of whether exposure to formaldehyde from occupational, residential and consumer products causes leukemia are critical.

KEYWORDS:

Epidemiology;	Evidence	integration;	Hazard	evaluation;	Mechanistic	studies;	Regulatory	science;
Toxicology								

Kimberly Wise White, Ph.D. | American Chemistry Council Senior Director, Chemical Products & Technology Division Kimberly_White@americanchemistry.com
700 2nd Street NE | Washington, DC | 20002
0: (202) 249-6707 C: (202) 341-7602
www.americanchemistry.com

From: Fritz, Jason [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F8D42341BD2241598226069F9623074A-FRITZ, JASON]

Sent: 5/21/2015 3:45:40 PM

To: Fritz, Jason [Fritz.Jason@epa.gov]; Gibbons, Catherine [Gibbons.Catherine@epa.gov]; Kraft, Andrew

[Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Caldwell, Jane [Caldwell.Jane@epa.gov]; Sonawane, Bob [Sonawane.Bob@epa.gov]; Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]; Cogliano, Vincent

[cogliano.vincent@epa.gov]

CC: Keshava, Nagalakshmi [Keshava.Nagu@epa.gov]

BCC: DCRoomPYN7771-North/ORD-NCEA-DC [DCRoomPYN7771@epa.gov]

Subject: FA LHP MOA draft markup discussion; 866-299-3188; 703-347-0332#; https://epa.connectsolutions.com/tpwg/

Attachments: Modes of action for Lymphoma revised draft 051515.docx; Appendix 1 lhp moa 051515.docx

Location: DCRoomPYN7771-North/ORD-NCEA-DC

Start: 5/28/2015 1:00:00 PM **End**: 5/28/2015 5:00:00 PM

Show Time As: Free

Hello everyone,

The purpose of this meeting is to go through the most recent revision (attached, from Jane C.) of the MOA/mechanistic event synthesis for the formaldehyde LHP cancer. I would like the focus to be on "big" picture changes, e.g. section organization, information content, clarity of presentation and arguments, consistency, background, speculation, etc.

To that end, everyone please read and become familiar with the revised draft synthesis section attached, prior to the meeting. This will be conducive to a good discussion and will facilitate stepping through important aspects of each section.



Modes of action for Lymphoma revis...

For reference, I am also attaching the Appendix which was provided by Jane to accompany this revised draft. This is FYI and may facilitate review/understanding of the MOA synthesis, but we will not be going over this section during the course of this markup meeting.



Appendix 1 lhp moa 051515.docx

Thanks, and we look forward to a constructive discussion next week! Jason Fritz, TPWG co-chair

Call-in and abode connect info:

866-299-3188; Redacted; https://epa.connectsolutions.com/tpwg/

From: Fritz, Jason [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

[FYDIBOHF23SPDLT]/CN=RECIPIENTS/CN=F8D42341BD2241598226069F9623074A-FRITZ, JASON]

Sent: 5/28/2015 7:00:28 PM

To: Fritz, Jason [Fritz.Jason@epa.gov]; Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]; Kraft, Andrew

[Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Rayhan, Sayeed [Rayhan.Sayeed@epa.gov]

BCC: DCRoomPYN7661-South/ORD-NCEA-DC [DCRoomPYN7661@epa.gov]

Subject: FA LHP MOA draft markup discussion; 866-299-3188; 703-347-0332#; https://epa.connectsolutions.com/tpwg/ **Attachments**: Modes of action for Lymphoma revised draft 051515_JF.docx; Modes of action for Lymphoma revised draft BRS May

27. late night.docx; Appendix 1 lhp moa 051515.docx; 28 May 2015 FA LHP MOA Parking lot.docx

Location: DCRoomPYN7661-South/ORD-NCEA-DC

Start: 6/2/2015 7:30:00 PM **End**: 6/2/2015 9:00:00 PM

Show Time As: Busy

Meeting #2 of the day, if necessary....

Hello super-number-one-best-dragon-force-strike-team-alpha members!

Yeah, okay so the name could use some work.

This is largest block of time I could find on Tuesday that everyone had available for making changes to the FA LHP MOA draft.

I will schedule a second meeting for the afternoon, in case we need it...

Thanks!

NOTE: a track changes draft from Bob has also been attached. Please do not cite, share, circulate or quote any of these documents with others.

Jf









28 May 2015 FA LHP MOA Parkin...

Appendix 1 lhp moa 051515.docx

Modes of action for Lymphoma revis...

Modes of action for Lymphoma revis...

Call-in and abode connect info:

866-299-3188; Redacted https://epa.connectsolutions.com/tpwg/

From: Fritz, Jason [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F8D42341BD2241598226069F9623074A-FRITZ, JASON]

Sent: 5/28/2015 6:45:54 PM

To: Fritz, Jason [Fritz.Jason@epa.gov]; Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]; Kraft, Andrew

[Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Rayhan, Sayeed [Rayhan.Sayeed@epa.gov]

BCC: DCRoomPYN7661-South/ORD-NCEA-DC [DCRoomPYN7661@epa.gov]

Subject: FA LHP MOA draft markup discussion; Redacted https://epa.connectsolutions.com/tpwg/

Attachments: 28 May 2015 FA LHP MOA Parking lot.docx; Appendix 1 lhp moa 051515.docx; Modes of action for Lymphoma

revised draft BRS May 27. late night.docx; Modes of action for Lymphoma revised draft 051515_JF.docx

Location: DCRoomPYN7661-South/ORD-NCEA-DC

Start: 6/2/2015 1:00:00 PM **End**: 6/2/2015 2:30:00 PM

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28 May 2015 FA LHP MOA Parkin...

Appendix 1 lhp moa 051515.docx

Modes of action for Lymphoma revis...

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Call-in and abode connect info:

Redacted https://epa.connectsolutions.com/tpwg/

Fritz, Jason [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From:

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F8D42341BD2241598226069F9623074A-FRITZ, JASON]

Sent: 5/28/2015 7:00:32 PM

Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara To:

[Glenn.Barbara@epa.gov]; Rayhan, Sayeed [Rayhan.Sayeed@epa.gov]

BCC: DCRoomPYN7661-South/ORD-NCEA-DC [DCRoomPYN7661@epa.gov]

FA LHP MOA draft markup discussion; Redacted https://epa.connectsolutions.com/tpwg/ Subject:

Attachments: Modes of action for Lymphoma revised draft 051515_JF.docx; Modes of action for Lymphoma revised draft BRS May

27. late night.docx; Appendix 1 lhp moa 051515.docx; 28 May 2015 FA LHP MOA Parking lot.docx

Location: DCRoomPYN7661-South/ORD-NCEA-DC

6/2/2015 7:30:00 PM Start: End: 6/2/2015 9:00:00 PM

Show Time As: Tentative

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Jf









28 May 2015 FA LHP MOA Parkin...

Appendix 1 lhp moa 051515.docx

Modes of action for Modes of action for Lymphoma revis...

Lymphoma revis...

Call-in and abode connect info:

Redacted https://epa.connectsolutions.com/tpwg/ From: Fritz, Jason [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F8D42341BD2241598226069F9623074A-FRITZ, JASON]

Sent: 5/26/2015 7:33:47 PM

CC: Keshava, Nagalakshmi [Keshava.Nagu@epa.gov]

Subject: FA LHP MOA draft markup discussion; Redacted; https://epa.connectsolutions.com/tpwg/

Attachments: Modes of action for Lymphoma revised draft 051515.docx; Appendix 1 lhp moa 051515.docx

Location: DCRoomPYN7771-North/ORD-NCEA-DC

Start: 5/28/2015 1:00:00 PM **End**: 5/28/2015 5:00:00 PM

Show Time As: Tentative

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Appendix 1 lhp moa 051515.docx

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From: Fritz, Jason [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F8D42341BD2241598226069F9623074A-FRITZ, JASON]

Sent: 5/21/2015 3:58:57 PM

To: Gibbons, Catherine [Gibbons.Catherine@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara

[Glenn.Barbara@epa.gov]; Caldwell, Jane [Caldwell.Jane@epa.gov]; Sonawane, Bob [Sonawane.Bob@epa.gov];

Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]; Cogliano, Vincent [cogliano.vincent@epa.gov]

BCC: DCRoomPYN7771-North/ORD-NCEA-DC [DCRoomPYN7771@epa.gov]

Subject: FA LHP MOA draft markup discussion; Redacted; https://epa.connectsolutions.com/tpwg/

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Appendix 1 lhp moa 051515.docx

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Call-in and abode connect info:

Redacted ; https://epa.connectsolutions.com/tpwg/

From: Birchfield, Norman [Birchfield.Norman@epa.gov]

Sent: 10/25/2016 1:31:31 PM

To: Birchfield, Norman [Birchfield.Norman@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Kraft, Andrew

[Kraft.Andrew@epa.gov]; Schlosser, Paul [Schlosser.Paul@epa.gov]; Cogliano, Vincent [cogliano.vincent@epa.gov]

Subject: Formaldehyde: Check in on BBDR text

Attachments: Ravi Revised Main.docx Location: DCRoomPYS11731-Capital

Start: 11/3/2016 8:00:00 PM **End**: 11/3/2016 9:00:00 PM

Show Time As: Busy

Call in no. Personal Privacy / Ex. 6

Purpose: to discuss the attached text provided by Ravi (Ravi gets back Nov 7th)



Ravi Revised Main.docx

From: Fritz, Jason [Fritz.Jason@epa.gov]

Sent: 5/28/2015 7:00:36 PM

To: Fritz, Jason [Fritz.Jason@epa.gov]; Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]; Kraft, Andrew

[Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Rayhan, Sayeed [Rayhan.Sayeed@epa.gov]

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Attachments: Modes of action for Lymphoma revised draft 051515_JF.docx; Modes of action for Lymphoma revised draft BRS May

27. late night.docx; Appendix 1 lhp moa 051515.docx; 28 May 2015 FA LHP MOA Parking lot.docx

Location: DCRoomPYN7661-South/ORD-NCEA-DC

Start: 6/2/2015 7:30:00 PM **End**: 6/2/2015 9:00:00 PM

Show Time As: Busy

Meeting #2 of the day, if necessary....

Hello super-number-one-best-dragon-force-strike-team-alpha members!

Yeah, okay so the name could use some work.

This is largest block of time I could find on Tuesday that everyone had available for making changes to the FA LHP MOA draft.

I will schedule a second meeting for the afternoon, in case we need it...

Thanks!

NOTE: a track changes draft from Bob has also been attached. Please do not cite, share, circulate or quote any of these documents with others.

Jf









28 May 2015 FA LHP MOA Parkin... Appendix 1 lhp moa 051515.docx

Modes of action for Lymphoma revis... Modes of action for Lymphoma revis...

Call-in and abode connect info:

Redacted https://epa.connectsolutions.com/tpwg/

Fritz, Jason [Fritz.Jason@epa.gov] From:

Sent: 5/28/2015 6:46:03 PM

To: Fritz, Jason [Fritz.Jason@epa.gov]; Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]; Kraft, Andrew

[Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Rayhan, Sayeed [Rayhan.Sayeed@epa.gov]

FA LHP MOA draft markup discussion; Redacted https://epa.connectsolutions.com/tpwg/ Subject: Attachments: 28 May 2015 FA LHP MOA Parking lot.docx; Appendix 1 lhp moa 051515.docx; Modes of action for Lymphoma

revised draft BRS May 27. late night.docx; Modes of action for Lymphoma revised draft 051515_JF.docx

Location: DCRoomPYN7661-South/ORD-NCEA-DC

Start: 6/2/2015 1:00:00 PM End: 6/2/2015 2:30:00 PM

Show Time As: Busy

Hello super-number-one-best-dragon-force-strike-team-alpha members!

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Jf









28 May 2015 FA LHP MOA Parkin...

Appendix 1 lhp moa 051515.docx Lymphoma revis...

Modes of action for Modes of action for Lymphoma revis...

Call-in and abode connect info:

https://epa.connectsolutions.com/tpwg/

From: Fritz, Jason [Fritz.Jason@epa.gov]

Sent: 5/21/2015 3:58:57 PM

To: Fritz, Jason [Fritz.Jason@epa.gov]; Gibbons, Catherine [Gibbons.Catherine@epa.gov]; Kraft, Andrew

[Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Caldwell, Jane [Caldwell.Jane@epa.gov]; Sonawane, Bob [Sonawane.Bob@epa.gov]; Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]; Cogliano, Vincent

[cogliano.vincent@epa.gov]

Subject: FA LHP MOA draft markup discussion; Redacted https://epa.connectsolutions.com/tpwg/

Attachments: Modes of action for Lymphoma revised draft 051515.docx; Appendix 1 lhp moa 051515.docx

Location: DCRoomPYN7771-North/ORD-NCEA-DC

Start: 5/28/2015 1:00:00 PM **End**: 5/28/2015 5:00:00 PM

Show Time As: Free

Hello everyone,

The purpose of this meeting is to go through the most recent revision (attached, from Jane C.) of the MOA/mechanistic event synthesis for the formaldehyde LHP cancer. I would like the focus to be on "big" picture changes, e.g. section organization, information content, clarity of presentation and arguments, consistency, background, speculation, etc.

To that end, everyone please read and become familiar with the revised draft synthesis section attached, prior to the meeting. This will be conducive to a good discussion and will facilitate stepping through important aspects of each section.



Modes of action for Lymphoma revis...

For reference, I am also attaching the Appendix which was provided by Jane to accompany this revised draft. This is FYI and may facilitate review/understanding of the MOA synthesis, but we will not be going over this section during the course of this markup meeting.



Appendix 1 lhp moa 051515.docx

Thanks, and we look forward to a constructive discussion next week! Jason Fritz, TPWG co-chair

Call-in and abode connect info:

https://epa.connectsolutions.com/tpwg/

From: Dishaw, Laura [Dishaw.Laura@epa.gov]

Sent: 4/12/2018 5:27:46 PM

To: Dishaw, Laura [Dishaw.Laura@epa.gov]; Luke, April [Luke.April@epa.gov]; Thayer, Kris [thayer.kris@epa.gov];

Shams, Dahnish [Shams.Dahnish@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara

[Glenn.Barbara@epa.gov]; Radke-Farabaugh, Elizabeth [radke-farabaugh.elizabeth@epa.gov]; Arzuaga, Xabier [Arzuaga.Xabier@epa.gov]; Kopylev, Leonid [Kopylev.Leonid@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Blessinger, Todd [blessinger.todd@epa.gov]; Wheeler, Matthew [wheeler.matthew@epa.gov]; Wang, Lily (Lihong) [wang.lily@epa.gov]; Morozov, Viktor [Morozov.Viktor@epa.gov]; Davis, Allen [Davis.Allen@epa.gov]; Gift, Jeff

[Gift.Jeff@epa.gov]; Mezencev, Roman [mezencev.roman@epa.gov]; Gibbons, Catherine

[Gibbons.Catherine@epa.gov]; Subramaniam, Ravi [Subramaniam.Ravi@epa.gov]

Subject: NAS workshops

Attachments: NAS-IRISreport.pdf; NAS mechanistic comments and workshop considerations

Location: DCRoomRRB51109-1; RTP-B230-Max20-NCEA/RTP-Bldg-B

Start: 4/18/2018 12:30:00 PM **End**: 4/18/2018 1:30:00 PM

Show Time As: Busy

Call in info (USE PHONE LINE FOR AUDIO):

DC: 202-991-0477 RTP: 984-444-7480 Conf ID: Redacted

Optional (only for sharing screens if it is helpful)

→ Join Skype Meeting

Trouble Joining? Try Skype Web App

<u>Help</u>		

We will meet to discuss ideas for the 2018 NAS workshops.

Attached are the NAS report from the "Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation" meeting and an email from Ravi with thoughts on possible topics.

From: Lidka Maslankiewicz/RIVM/NL [lidka.maslankiewicz@rivm.nl]

Sent: 4/9/2018 12:29:58 PM

To: Lidka Maslankiewicz/RIVM/NL [lidka.maslankiewicz@rivm.nl]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Kraft,

Andrew [Kraft.Andrew@epa.gov]; Paul Janssen/RIVM/NL [paul.janssen@rivm.nl]; Theo Vermeire/RIVM/NL

[theo.vermeire@rivm.nl]

Subject: Information Update - Description has changed: Discussion on and formaldehyde assessment (IRIS Toxicological

Review of Formaldehyde (Inhalation))

Attachments: ATT00001.htm; c181708.ics

Start: 5/9/2018 1:00:00 PM **End**: 5/9/2018 2:30:00 PM

Show Time As: Busy

Recurrence: (none)



Information Update - Description has changed: Discussion on and formaldehyde assessment (IRIS Toxicological Review of Formaldehyde (Inhalation))

05/09/2018 -

No Location Information

Lidka Maslankiewicz

has sent updated information; description has changed

Required:

glenn.barbara@epa.gov, Kraft.Andrew@epa.gov, Paul Janssen/RIVM/NL@RIVM, Theo Vermeire/RIVM/NL@RIVM

Description

Agenda:

- 1. Round of mutual introduction
- 2. Presentation of US EPA and NL ongoing activities on formaldehyde risk assessment.
- 3. NL questions on 2010 draft IRIS toxicological review on formaldehyde:
- Are there any new developments in the process at EPA of evaluating formaldehyde?
- Would it be possible for us to use the data and concept, with agreed referencing?
- Do you plan any additional modelling to be done for deriving the unit risks from the NCI-cohort data, according to the advice from National Research Council?
- Do you plan to derive unit risk derived from animal data?
- 4. AOB

Please,	call:	
Perso	onal Matters / Ex. 6	

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- Do you plan to derive unit risk derived from animal data?
- 4. AOB

Please, call:

Personal Matters / Ex. 6

From: Soto, Vicki [Soto.Vicki@epa.gov]

Sent: 4/21/2017 5:49:15 PM

To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]

CC: Cunningham, Taukecha [Cunningham.Taukecha@epa.gov]

Subject: Fwd: Formaldehyde Tox Review Merged Part A & B (WP-40W) Read for Author Review (Due 4/21/17)

Attachments: image001.png; ATT00001.htm; image002.png; ATT00002.htm; image003.png; ATT00003.htm; image001.png;

ATT00004.htm; image001.png; ATT00005.htm; Formaldehyde Main Text - IRD.docx; ATT00006.htm

Hi

I did not have a chance to check these over but I will look in a bit. I had some car issues today and have been at the dealers: (I know you are anxious to take a look.

Vicki

Sent from my iPhone

Begin forwarded message:

From: NCEA_TSS < NCEA_TSS@epa.gov > Date: April 21, 2017 at 1:46:05 PM EDT

To: "Cunningham, Taukecha" < <u>Cunningham. Taukecha@epa.gov</u>>

Cc: "Schaffner, Thomas" < Schaffner. Thomas@epa.gov>, "Walker, Lisa"

< <u>Walker.Lisa@epa.gov</u>>, "Zwayer, Bette" < <u>zwayer.bette@epa.gov</u>>, "Tackett, Linda"

<Tackett.Linda@epa.gov>, "Kraft, Andrew" <Kraft.Andrew@epa.gov>, "Glenn, Barbara"

< <u>Glenn Barbara@epa.gov</u>>, "Soto, Vicki" < <u>Soto Vicki@epa.gov</u>>, "Konoza, Terri"

<Konoza. Terri@epa.gov>, NCEA TSS <NCEA TSS@epa.gov>

Subject: Formaldehyde Tox Review Merged Part A & B (WP-40W) Read for Author Review (Due 4/21/17)

Dear Taukecha,

Deliberative Process / Ex. 5

Please let TSS know if you have any questions. Send any further correspondence on this request to NCEA TSS@epa.gov.

Thank you,

Kathleen Bland

Technical Support Services

Highlight Technologies, LLC contractor for U.S. EPA, NCEA 26 W. Martin Luther King Ave, Rm A-G41 Cincinnati, OH 45220

From: Cunningham, Taukecha

Sent: Wednesday, March 29, 2017 5:31 PM

To: Heing, Dan

Cc: NCEA_TSS; NCEA_TSS_SG; Schaffner, Thomas; Walker, Lisa; Zwayer, Bette; Tackett, Linda; Kraft,

Andrew; Glenn, Barbara; Soto, Vicki; Konoza, Terri

Subject: RE: Formaldehyde Tox Review, Part a & b; Revised Contractor Schedule

Dan,

Yes this is exactly what we need done and please feel to let us know if you have any other questions.

Thanks,

Taukecha Cunningham Information Management Specialist U.S. EPA/ORD National Center for Environmental Assessment

703-347-0294

Cunningham. Taukecha@epa.gov

From: Heing, Dan

Sent: Wednesday, March 29, 2017 5:28 PM

To: Cunningham, Taukecha < Cunningham. Taukecha@epa.gov>

Cc: NCEA_TSS < NCEA_TSS@epa.gov>; NCEA_TSS_SG < NCEA_TSS_SG@epa.gov>; Schaffner, Thomas

<<u>Schaffner.Thomas@epa.gov</u>>; Walker, Lisa <<u>Walker.Lisa@epa.gov</u>>; Zwayer, Bette

<zwayer.bette@epa.gov>; Tackett, Linda <<u>Tackett.Linda@epa.gov</u>>; Kraft, Andrew

< Kraft. Andrew@epa.gov >; Glenn, Barbara < Glenn. Barbara@epa.gov >; Soto, Vicki

<Soto.Vicki@epa.gov>; Konoza, Terri < Konoza.Terri@epa.gov>

Subject: Re: Formaldehyde Tox Review, Part a & b; Revised Contractor Schedule

Taukecha,

Deliberative Process / Ex. 5

Open Tell my barban count the my barban count mand or count AT (arth 14 parks to come

Please advise and thanks.

Dan

Dan Heing | Project Manager

Office 513.569.7725 Mobile 513.377.1130

dheing@HighlightTech.com | www.HighlightTech.com